CONFERENCE ON DISARMAMENT

CD/988
CD/CW/WP.291
20 April 1990

Original: ENGLISH

LETTER DATED 19 APRIL 1990 FROM THE PERMANENT MISSION OF INDIA ADDRESSED TO THE SECRETARY-GENERAL OF THE CONFERENCE ON DISARMAMENT TRANSMITTING A DOCUMENT "REPORT OF THE NATIONAL TRIAL INSPECTION CONDUCTED BY INDIA"

I have the honour to enclose a document entitled "Report of the National Trial Inspection conducted by India". I would be grateful if this could be circulated in the Conference on Tuesday, 24 April 1990, as a CD document.

(Signed) ANIL WADHWA

GE.90-60808/6061A

REPORT OF THE NATIONAL TRIAL INSPECTION CONDUCTED BY INDIA.

Introduction

This document presents the results of the National Trial Inspection that was carried out during three visits to the production facility of Searle India, Bombay, a multi-purpose unit manufacturing a variety of drugs. The facility of M/s Searle India was selected for trial inspection purpose. The facility is manufacturing diisopyramide phosphate from DIPC alcohol which is initially converted to DIPC hydrochloride (DIPC Hcl) and then to nitride pyramixetosylate. Another product, propantheline bromide is also produced by esterification of xanthanoic acid with DIPC Hcl. The feedstock, DIPC alcohol and the chemical DIPC Hcl are listed in the section of Schedule [2] chemicals.

The inspection served to test the adequacy of the system of verification provided in the draft Chemical Weapons Convention, in the context of its objectives to ensure 'A'. The inspection also provided an opportunity to test the degree of intrusiveness required to conduct the verification procedures even while protecting commercial confidentiality.

The results of the Indian national trial inspection presented below, conform generally to the format contained in document CD/CW/WP.213.

A. GENERAL APPROACH

1. Objectives of national trial inspection

The objectives of the National Trial Inspection were those set forth in document CD/CW/WP.213.

2. Provisions in the draft convention under which the trial inspections took place

These were in accordance with the provisions contained in the Annex to Article VI[2] of the rolling text of the draft Chemical Weapons Convention.

3. Type of on-site inspection

An initial visit by the inspection team was made on April 8, 1989 for familiarization purposes, for obtaining information relevant for planning the future verification activities at the inspection, to determine the precise inspection plan and to work on the facility attachment agreements. A second visit by a very small

group of inspectors took place on July 4 and 5, 1989 in order to finalize the facility attachment agreement. The final inspection took place on August 9 and 10, 1989.

4. Advance information

a) Declarations

At the time of the initial and second visit, the firm made the relevant declarations concerning the production during the past 5 years of the above mentioned chemicals and made available all other relevant information required by the inspection team.

b) Agreement on inspection procedures

The team negotiated and finalized a facility attachment based on the "Model for an agreement relating to facilities producing, processing or consuming chemical listed in Schedule [2] (CD/874 pp 125-128), with which the management of the private sector firm, Searle India Ltd, did not have any problems.

5. Type of facility inspected

The facility inspected is a multi-purpose plant manufacturing specialty chemicals related to bulk drugs and intermediates.

6. Types of declared activity at the facility.

The facility handles and produces small volume of Schedule [2] chemicals i.e. maximum 1.6 MT per year. These chemicals are stored along with other solvent and chemicals. The basic raw material, DIPC alcohol, is imported once or twice a year and consumed in a short period of 4 to 8 batch runs, as and when there is demand for the drugs.

7. Actual activity at the facility

At the time of the initial and second visits, the facility was manufacturing other chemical materials not related with Schedule [2] items. The inspecting team decided deliberately to schedule the final visit for a routine on-site inspection, to coincide with the batch run in which scheduled chemicals were processed and produced in order to check the efficacy of the verification process.

B. **DETAILED APPROACH**

1. Composition of the inspection team

The team consisted of the following persons-

i) Team Leader: Joint Secretary(Chem), Ministry of Petroleum & Chemicals, Government of India.

ii) one chemist;

iii) one chemical analyst;

iv) one chemical engineer;

v) one chemical technologist; and

vi) one auditor.

Besides the requisite technical expertise for conducting a trial inspection, the team included representatives from the Ministry of Petroleum & Chemicals, the nodal Ministry in Government of India for the chemical industry, the Ministry of External Affairs which oversees the negotiations on the draft CW Convention.

The team negotiated the inspection mandate after explaining the Chemical Weapons Convention with the company's team which consisted of the following officials:

i) Production Director

ii) Director, Research & Development

iii) Works Manager

iv) Production Manager(Chemicals)

v) Manager, Quality Assurance

vi) Production Services Manager.

2. The negotiation covered the following subjects

i) The plant area to which the inspection team should have access for routine on-site inspection, including the collection of samples for analysis.

ii) Records to be made available to the inspecting agency.

iii) Facilities and services to be provided by the company.

iv) Right of the inspectors to examine the operations of the company pursuing the identical processes.

3. Inspection equipment

The portable equipment carried by the inspection team for the routine inspection included liquid and gas samplers, an auto-titrator, a gas-liquid chromatograph, PH meters and refracto meters. All the other technical equipment used was provided by the company from its in-house R&D laboratory.

4. Activities prior to the arrival of the inspection team on site.

The date of the routine on-site inspection was chosen on the basis of mutual convenience and after confirming that the batch runs of Schedule [2] chemical would be undertaken by the company on the said dates.

5. Advance preparation on site

The Managing Director of the Company informed the team leader of the arrival of the imported DIPC alcohol and the likely dates of the production schedule. The visit was undertaken on a day when a new batch was taken up for production.

6. Escort and points of contact arrangements.

The company provided adequate staff to act as escort as also to answer the routine queries made by the inspecting team. The company designated certain officials as the contact persons for the duration of the trial inspection.

7. Other participants

A representative from the Disarmament Unit of the Ministry of External Affairs, Government of India was present during the routine inspection.

8. Duration of initial visit and inspection

- Initial visit - one day, (5 persons).

- Preparatory facility attachment - two days, (3 persons).

- Actual inspection - 1 day (4 persons)

- Inspection report programme - 2 days (3 persons).

9. Measures to protect confidential information

The inspectorate discussed with the company officials the various types of confidential information which fall under the following. The four levels of classification:

a) releasable to the public

b) releasable to the States parties to the convention.

c) limited to the technical secretariat; and

d) available to inspectors only - not to be removed from the company premises.

Detailed process diagrams and documents incorporating procedures were not removed from the site.

10. Opening conference

The team leader spelt out the purpose of the national trial inspection to the members of the inspection team and company representatives. The Company's Managing Director, along with his identified officials discussed their activities at the facility and the various safety measures adopted. The opening conference lasted for about two hours.

11. Types of records needed and/or audited.

The company maintains good records of the raw materials including the imported materials. The company made available to the inspection team the following plant protection records and financial statements:

Plant production records

i) Log books, being maintained on a daily basis, showing product batch numbers in progress and kettle numbers in use of various batches of products in the factory.

ii) Production record card, maintained batch-wise, showing production of each batch, giving details of materials charged.

iii) Production report of various products, along with batch numbers, prepared on a monthly basis, giving details of monthly and cumulative production. This also gives process information.

iv) Plant information is given in the above reports.

v) Production report for individual batches of DIPC Hydrochloride and N.P. Tosylate, etc. are maintained and were made available to the inspection team.

Financial statements

Regarding receipt and issue of diisopropyl amino ethanol (raw material), the following documents/records are maintained:

1. Purchase order on the foreign supplier.

2. Opening of Letter of Credit.

3. Bill of Entry at the time of receipt of material in India, i.e. the Excise/Custom documents.

4. Railway Receipt at the time of receipt, on site, at the Searle India factory.

5. Entries in the Stores Ledger.

6. To have strict control for the use of diisopropyl amino ethanol, the following registers are maintained:

   a) Stock register of diisopropyl amino ethanol and DIPC Hcl.

   b) Note book for special enclosure inside the stores for locking/unlocking at the time of receipt and issue of the material in/from the stores.

7. As soon as diisopropyl amino ethanol is converted into intermediate products, the production department keeps a record of the same and in case the material is not used immediately, it is transferred to the stores for safe custody, as

per established procedure, and got reissued as and when required.

8. The record of products viz. diisopyramide Technical and propantheline bromide, transferred to the Searle India unit at Ankleshwar or for outside sale under Excise Gate pass, as per Excise Rules are maintained.

12. Plant orientation tour.

The orientation tour on the plant covered the total facility excepting the pharmaceutical manufacturing, packing and storage sections, as per the attached site plan vide Annexure I.

13. Inspection of areas and facility equipments

The following facility area was inspected in detail:

1. Raw material storage.

2. Chemical manufacturing and plant room.

3. Effluent treatment.

4. Drying annex.

5. General store.

6. Incinerator shed.

7. R&D Centre.

8. Quality Control Lab.

At the time of the initial familiarization visit, the inspection team had also been taken to the areas mentioned above. At that stage, no special area had been earmarked within the stores for keeping the Schedule [2] raw material. The team advised the Company's Management to store the Schedule [2] chemical feedstock (which is imported) in a more safe and secure location. The Company acted on this suggestion and during the routine on-site inspection it was observed that the chemical feedstock had been placed within the storage area in an enclosure especially earmarked for it and to which access was confined to authorized personnel only.

14. Inspection of areas and facility equipments.

In the presence of the inspection team, one batch was charged and the operation was followed up for the next two days by one member of the team to confirm the yield of the batch. During the inspection, the inspectors paid special attention to complete details in order to ensure that the facility was not involved in any undeclared activity. The inspection team was satisfied with the records and details made available by the facility representatives.

15. Sampling and sample taking procedure

The sampling was mainly performed by the company's personnel in the presence of the inspectors, based on the agreed areas of sampling. The samples analyzed in the company's laboratory included the raw materials, stack and effluent water samples, as also the finished products.

The company also agreed to monitor air samples at the facility during the production process as well as samples of water used for cleaning the vessels after the production of each batch.

16. Handling of samples

As per the negotiated facility attachment with the company, the inspection team supervised both the sampling and the on-sight handling of the samples. The company made available the analytical data of the identified samples.

17. Types of samples

The analysis of the samples was done by the company following a standard procedure which was discussed with the inspection team and found to be adequate for the purpose.

18. Types of analysis

During the negotiation of the facility attachment, the company agreed on the following types of analysis -

- The raw materials and the products to ensure that they were in conformity with the chemicals declared.

- The finished product analyzed as per the standard procedure.

- The air and water samples analyzed as per the statutory requirements of the State Government which were found to be comprehensive.

19. Documentation of the inspection

The basic material flow and process diagram was made available to the inspection team. A report was prepared by the inspection team based on the general data given by the company for input material and the finished product. The company management desired that the process details be considered as classified information and should not be permitted to be taken out of the premises. For this purpose, the company agreed to provide space for retaining the documents under lock and key of the inspection team.

20. Evaluation by inspectors

The following information were gathered during the visit of the evaluation team.

- The possibility of undeclared conversions between routine inspections;

- The level of accuracy of the data made available by the company.

- The various difficulties that could be encountered during the actual inspection. This aspect was discussed in detail after the inspection with the company management.

21. Closing conference

The closing conference lasted for approx. two hours and centered round the aspects outlined in Item 20. The question of level of confidentiality was discussed. The company desired that the analyses of the samples be done for the present in the in-house facilities located at the production site itself.

22. Anomalies, disputes and complications

During the inspection, there were no anomalies, disputes and complications.

23. Report of the inspection team

The report was prepared off-site a week following the inspection. The team was of the view that in the case of routine, on-site inspections, no violations were

found or no anomalies, disputes or complications existed, the format of the report could be shortened and simplified.

24. Impact of the inspection on facility operations

The inspection did not affect the normal production programme of the company.

C. SPECIFIC ASPECTS - CONCLUSIONS

1. The inspection mandate

The facility attachment was based on the understanding that it would be only that part of the facility which would be processing or consuming the Schedule [2] chemicals, which is the subject of inspection. The facility attachment was worked out on this basis and the inspection was conducted accordingly.

2. Composition of the inspection team

The team chosen for the trial inspection, excluding the team leader, consisted of the following :

- one chemist;
- one chemical analyst;
- one chemical engineer;
- one chemical technologist; and
- one auditor.

This team was found to be adequate for the national trial inspection. A large part of the time of the inspection team was consumed in verifying the records during the trial inspections, as it included total audit of the documentation relevant to the declared Schedule II chemicals. Since each batch takes approximately 60 hours, it would take approximately three working days of an inspection team to perform the inspection appropriately.

3. Inspection equipment

During the trial inspections, no inspection equipment was taken and only routine inspection was done due to the intermittent schedule of production of Schedule [2] chemicals in the facility.

4. Activities prior to the arrival of the inspection team on-site

The production and consumption of the Schedule [2] chemicals at the production site is not of continuous nature and is undertaken based on the demand for the drug in the market. This inspection was undertaken after the company confirmed receipt of the imported DIPC alcohol and their production schedule.

5. Advance preparations on site

The company arranged for a room for the opening and closing of the conference and cooperated fully with the inspection team.

6. Escort and Point of contact arrangements.

The Management of the company cooperated fully and the Managing Director himself escorted the inspection team during the routine, on-site inspection and was available for the entire duration of the from the day of the final inspection.

7. Other participants

A representative from the Disarmament Unit of the Ministry of External Affairs, Government of India was present during the routine inspection. His presence ensured familiarity of the inspection team with the draft Chemical Weapons Convention and facilitated the adoption of procedures in consonance with the guidelines for inspection elaborated so far under the Convention.

8. Duration of initial visit and inspection

The duration of the initial visit and negotiation of the facility attachment took a total of three days and the actual, routine on-site inspection took another day, with two additional days for completion of laboratory analyses, this appears be reasonable to allow for inspection of most facilities.

9. Measures to protect confidential information

A detailed discussion was held during the negotiation under the four level classification system for confidential information. Agreement was arrived on which information came under each category. Necessary arrangements were made for maintaining confidentiality during the inspection. The Managing Director of the company was particularly concerned with the level (d) concerning the information "available to inspectors

only - not to be removed from the company premises". The company provided an on-site plan of the complex and a detailed flow chart for the production of the drug on a clear understanding that it contained confidential information not to be divulged to any outsider. The company insisted that these documents should not be removed from the company site and to be returned to their Chief Chemist at the end of the inspection. The company desired that the following information be also covered under level (d) -

- The annual consumption/production;

- Purchase price of feedstock chemicals;

- Customer, buyer product reports.

10. Opening conference

Depending on the complexity of the operation, the opening conference could last 60-90 minutes.

11. Types of records needed and/or audited

Conscious of this fact that the facility inspected handles Scheduled chemicals in a non-continuous manner through a batch process and that future inspection may not be possible exactly at the time when such a batch process is in progress, the Inspection Team paid special attention to the examination of documentation and material balance.

The inspection team felt that the company maintains good records of raw materials and final product. These records were well documented.

The inspection team concluded that the records examined were consistent with the company's declaration. It was satisfied that the company did not undertake production of any other undeclared chemicals and that the scheduled chemical was used for the production of drugs only in one facility. The yield, however, was persistently low since the very inception of the company and this was brought to the notice of the management. The latter explained that they are seized with this problem and are trying to find out ways and means to improve the yield.

12. Plant orientation tour

The plant orientation tour lasted for about 70 minutes and was found to be extremely useful for familiarizing

the inspection team with the physical layout of the facility.

13. Inspection of areas and facility equipment

A general inspection of the plant is necessary to enable the inspection team to understand whether the declared chemical process is being followed and whether there are possibilities of production of undeclared items. The inspection team felt that at the opening conference itself, the question of inspecting the site along with the full lay-out of the factory and the equipments positioning be discussed to make the inspection effective. The area and the facility equipment inspections are as indicated under Item B-13.

14. Inspection of operation procedures

In order to verify the declared chemical production process, it was necessary for the inspection team to be present at the time of charging of the chemicals, sampling and at the concluding stage of the reaction process.

15. Sampling and sample taking procedure

Use of sample taking devices and monitoring equipment were considered very useful to confirm the production process and the composition of chemicals under processing. The sampling procedure has to be in tune with the type of facility being inspected. Three samples required to be collected for cross-checking purposes. The sampling of the stack and effluent water would need special devices which could determine nanogram levels of the chemical in question.

The company officials stressed that while the company would cooperate in providing facilities for collecting and analyzing the samples as were available with them, the inspection team would be free to use their own methods of analysis, standards and additional equipments, if required.

16. Handling of samples

The company expressed no difficulties with regard to the method of handling of samples as contained in Item B-16. The company, however, insisted that the technical information with regard to the process details be given suitable protection and the samples drawn should be handled, keeping this in mind.

17. Analysis of samples

The ready access to the analytical procedure and availability of a good analytical laboratory is indispensable for precise analysis of samples. Before trial inspection takes place, it would be imperative to ensure that the analytical procedure, the reference samples and suitable analytical facilities are lined up for processing of the samples.

18. Types of analysis

The company, while agreeing to provide all facilities for analysis of the samples, stressed the need for confidentiality of the information.

As brought out earlier, the production of the drugs are need-based and the facility is never in continuous use. While negotiating the facility attachment, the company expressed no objection to drawing up of the samples of the feed chemicals of the final products. In order to ensure that the facility is used only for the declared chemicals, it would be necessary to arrange on-site analysis, adopting negative proof methods to ensure that at the time of inspection, other chemicals in Schedule [2] or Schedule [1] were not being manufactured.

19. Documentation

The inspection team felt it essential to consult the Management of the facility with regard to the level of confidentiality of the information before these could be released for use by various authorities. For this purpose, it would be advisable to have the inspection reports fully seen and cleared with the concerned company for further processing. This is considered imperative as the various technologies developed to manufacture products at higher efficiencies deserve protection from competitors. The inspection team noticed that the management of the facility cooperated well with them on the clear understanding that they do not run the risk of losing the confidentiality of their process know-how and other important privileged, commercial information.

20. Evaluation by inspectors

The Inspection Team felt that before undertaking the inspection, a detailed discussion amongst the team members was essential to divide responsibility amongst its members to cover the various facets laid down for

the inspection. This, facilitates the actual inspection, collection of samples, analysis of the samples, audit inspection of the various documents and the other related activities.

21. Closing conference

The closing conference was considered essential to fill in the various gaps identified during the process of the trial inspection. It is desirable to have a detailed closing conference with the designated staff of the facility.

22. Anomalies, disputes and complications

In the inspection, there was no disputes, complications and anomalies primarily because of the excellent cooperation extended by the top management of the facility. There was little chance of complication as the production and use of Schedule [2] raw materials was confined to one facility only. The abnormality identified by the inspection team, namely, the extremely low yield of the final product, is sought to be rectified by the management through concerted R&D efforts.

23. Report of the inspection team

The inspection team generally felt that the report could be prepared keeping the confidentiality aspect in mind and would suitably sub-divide the report to safeguard the confidentiality of the process. The classification would be based on the judgement with regard to the level of information which could be made public and the other which could be made available to the States Parties to the convention or to the Inspectors only during the inspection, and kept under safe custody at the facility premises.

24. Impact of the inspection on facility operations

During the inspection of the facility, there was no loss of production as it was easy to sample both the raw materials which were fed into the reactors and the finished product which became available at the end of the 60 hour cycle. There was no scope for any intermediate sample collection as the reaction was performed under closed conditions.

It was only during the routine,on-site inspection that the designated staff of the company had to spare half a day to escort the inspection team in the facility and

answer to the various queries raised during the process of inspection.

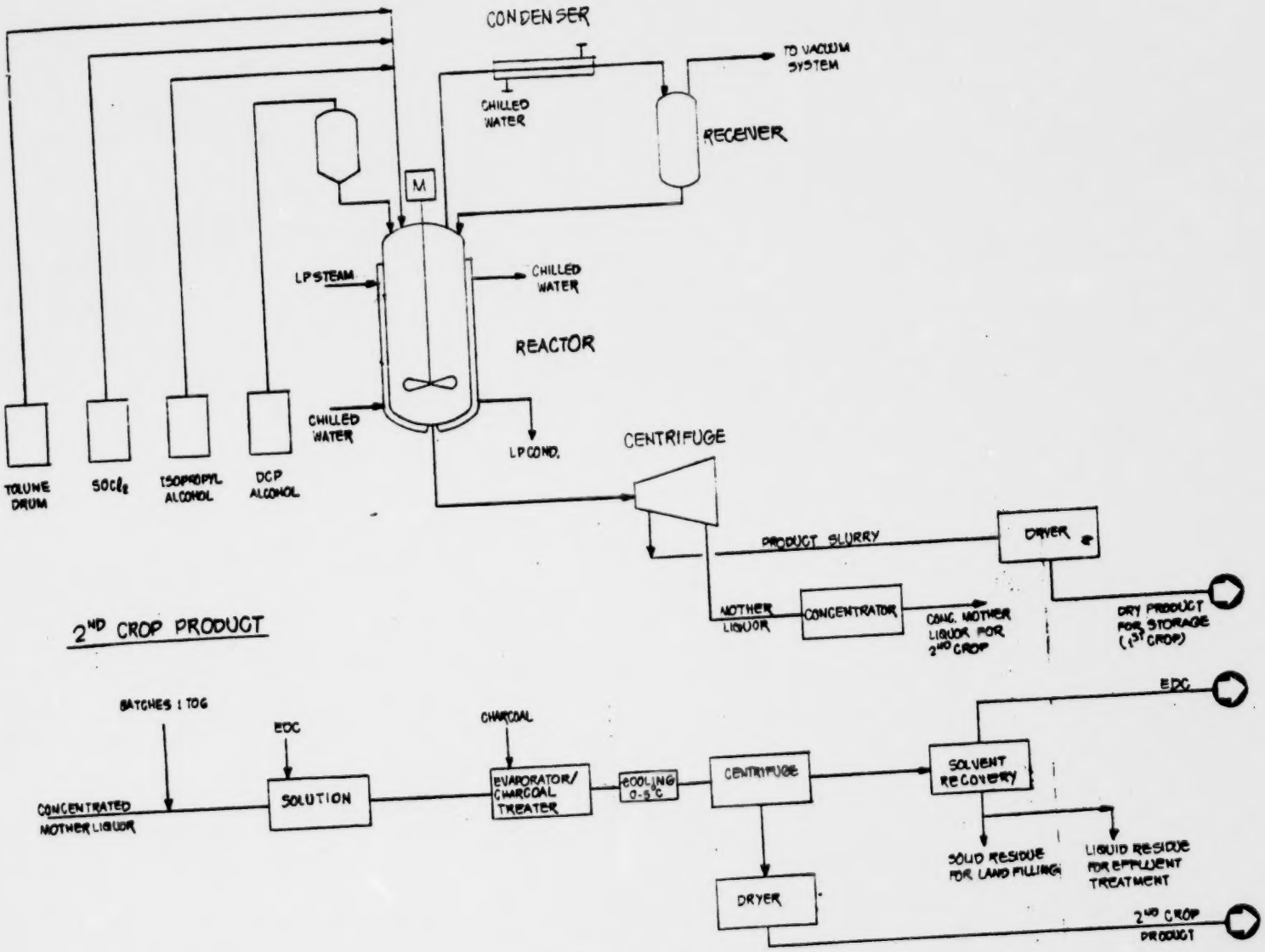
D. SUGGESTIONS FOR REFINING THE VERIFICATION PROCEDURES

1. Inspections carried out when the scheduled chemical is not being produced or processed in the production facility should not deter the inspectors from having access to the facility for on-site verification of the process equipment. Such inspection should, however, rely upon data verification and material balance and stack sample analysis to eliminate the possibility of the manufacture of any of the scheduled chemicals.

2. The international inspectors shall submit a report of their findings to the Director General of the Technical Secretariat and on the basis of which it would be determined whether the activities of the facility inspected are in conformity or otherwise with the provisions of the Chemical Weapons Convention. A standardized format listing a 'Yes' or 'No' type questionnaire, with brief comments by the inspectors as to how they arrived at their conclusions could be elaborated to overcome any difficulties regarding the interpretation of the inspection of any facility. In case the facility inspected is in order, the inspectors report could be brief and factual, rather than descriptive.

3. During the verification process, the international inspectors will handle chemicals for sampling and analyses. For ensuring safety, the inspectors could adhere to the safety procedures already in force within the facility, and in conformity with the regulations laid down by the national authorities concerned.

SITE PLAN



BLOCK FLOW DIAGRAM FOR DIPC - HCl